

SENATE BILL No. 475

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-26; IC 21-45-7; IC 34-30-2-84.1; IC 35-48-4.

Synopsis: Hemp oil registry for the treatment of epilepsy. Establishes a hemp oil registry for certain physicians, individuals, and caregivers for the use of hemp oil in the treatment of a child with intractable epilepsy. Establishes a pilot study registry for physicians interested in studying the use of hemp oil in the treatment of intractable epilepsy. Requires the state department of health to develop and maintain both registries. Provides civil, criminal, and administrative immunity for physicians in the use of hemp oil in the treatment of intractable epilepsy if certain requirements are met. Exempts caregivers and individuals from criminal penalties for possession or use of hemp oil if the caregivers and individuals are registered with the state department and are using the hemp oil for the individual and in the manner approved for registration. Encourages state educational institutions to research the use of hemp oil in the treatment of intractable epilepsy.

Effective: July 1, 2015.

Tomes

January 14, 2015, read first time and referred to Committee on Health & Provider Services.



First Regular Session 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

SENATE BILL No. 475

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 16-18-2-48.7 IS ADDED TO THE INDIANA
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 2015]: **Sec. 48.7. "Caregiver", for purposes**
4 **of IC 16-42-26, has the meaning set forth in IC 16-42-26-1.**

5 SECTION 2. IC 16-18-2-169.5 IS ADDED TO THE INDIANA
6 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
7 [EFFECTIVE JULY 1, 2015]: **Sec. 169.5. "Hemp oil", for purposes**
8 **of IC 16-42-26, has the meaning set forth in IC 16-42-26-2.**

9 SECTION 3. IC 16-18-2-191.7 IS ADDED TO THE INDIANA
10 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
11 [EFFECTIVE JULY 1, 2015]: **Sec. 191.7. "Intractable epilepsy", for**
12 **purposes of IC 16-42-26, has the meaning set forth in**
13 **IC 16-42-26-3.**

14 SECTION 4. IC 16-18-2-272 IS AMENDED TO READ AS
15 FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 272. (a) "Patient", for
16 purposes of IC 16-27-1, has the meaning set forth in IC 16-27-1-6.



(b) "Patient", for the purposes of IC 16-28 and IC 16-29, means an individual who has been accepted and assured care by a health facility.

(c) "Patient", for purposes of IC 16-36-1.5, has the meaning set forth in IC 16-36-1.5-3.

(d) "Patient", for purposes of IC 16-39, means an individual who has received health care services from a provider for the examination, treatment, diagnosis, or prevention of a physical or mental condition.

(e) "Patient", for purposes of IC 16-42-26, has the meaning set forth in IC 16-42-26-4.

SECTION 5. IC 16-18-2-282, AS AMENDED BY P.L.6-2012, SECTION 111, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 282. (a) "Physician", except as provided in subsections (b) ~~and (c)~~, **through (d)**, means a licensed physician (as defined in section 202 of this chapter).

(b) "Physician", for purposes of IC 16-41-12, has the meaning set forth in IC 16-41-12-7.

(c) "Physician", for purposes of IC 16-37-1-3.1 and IC 16-37-3-5, means an individual who:

(1) was the physician last in attendance (as defined in section 282.2 of this chapter); or

(2) is licensed under IC 25-22.5.

(d) "Physician", for purposes of IC 16-42-26, has the meaning set forth in IC 16-42-26-5.

~~(d)~~ (e) "Physician", for purposes of IC 16-48-1, is subject to IC 16-48-1-2.

SECTION 6. IC 16-42-26 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 26. Drugs: Study and Use of Hemp Oil for the Treatment of Epilepsy Program

Sec. 1. As used in this chapter, "caregiver" refers to a parent, legal guardian, health care representative, or custodian of an individual who is:

(1) less than eighteen (18) years of age; or

(2) at least eighteen (18) years of age but started treatment with hemp oil described under this chapter when the individual was less than eighteen (18) years of age;

and who has been diagnosed with intractable epilepsy by a physician.

Sec. 2. As used in this chapter, "hemp oil" means the oil from a hemp plant.

Sec. 3. As used in this chapter, "intractable epilepsy" means a



1 seizure disorder that has been diagnosed by a physician in a patient
 2 who has not responded to at least three (3) other seizure disorder
 3 treatment options.

4 Sec. 4. As used in this chapter, "patient" refers to an individual
 5 who is:

- 6 (1) less than eighteen (18) years of age; or
- 7 (2) at least eighteen (18) years of age but started treatment
- 8 with hemp oil described under this chapter when the
- 9 individual was less than eighteen (18) years of age;
- 10 and who has been diagnosed with intractable epilepsy by a
- 11 physician.

12 Sec. 5. As used in this chapter, "physician" means an individual
 13 who:

- 14 (1) is licensed under IC 25-22.5;
- 15 (2) is board certified in neurology; and
- 16 (3) is affiliated with a state educational institution.

17 Sec. 6. (a) The state department shall develop and implement a
 18 hemp oil registry for the registration of:

- 19 (1) physicians;
- 20 (2) patients; and
- 21 (3) caregivers;

22 for the use of hemp oil in the treatment of patients with intractable
 23 epilepsy.

24 (b) The hemp oil registry must include a secure, electronic
 25 online data base that is accessible by law enforcement agencies in
 26 order to verify the registration of an individual.

27 (c) The state department shall register a physician who:

- 28 (1) meets the requirements of this chapter;
- 29 (2) submits a completed registration form issued by the state
- 30 department; and
- 31 (3) pays the registration fee.

32 (d) The state department shall register and issue an individual
 33 described in subsection (a)(2) or (a)(3) a registration card under
 34 this section only if the individual meets the following requirements:

- 35 (1) The individual is:
 - 36 (A) at least eighteen (18) years of age; or
 - 37 (B) a patient.
- 38 (2) The individual is an Indiana resident.
- 39 (3) The individual provides a certified statement by a
- 40 physician registered under this section that a patient in the
- 41 care of the caregiver meets the following requirements:
 - 42 (A) The patient has been examined and diagnosed by the



physician to have intractable epilepsy.

(B) The patient has been recommended by the physician for treatment by hemp oil for the intractable epilepsy.

(C) The patient is eligible to be included in the physician's pilot study registry under section 8 of this chapter.

(4) The patient submits a completed registration application.

(5) The patient pays the registration fee set by the state department.

(e) The state department shall develop the hemp oil registration application. The registration application for a caregiver must ask for the following information:

(1) The caregiver's name and address.

(2) The patient's name and address.

(3) A copy of the caregiver's valid government issued photo identification card.

(4) Any other relevant information the state department considers necessary to implement this section.

(f) The state department shall charge a registration fee of not more than fifty dollars (\$50) for an individual's initial registration under this section to cover the costs of implementing and administering the registry.

(g) Registration under this section is valid for one (1) year from the date of issuance. The state department shall renew registration under this section for an individual if the initial registration is current or has been updated by the individual and the individual continues to meet the registration requirements under this chapter. The state department shall charge a renewal fee of not more than twenty-five dollars (\$25).

Sec. 7. When a patient or caregiver registers for the hemp oil registry, the state department shall contact and provide the local department of health where the patient or caregiver resides with the following information:

(1) The name and address of the patient or caregiver.

(2) Identifying information contained on the patient's or caregiver's registration card.

(3) Any other information the state department determines is necessary to disclose.

Sec. 8. (a) The state department shall establish and maintain a pilot study registry for the monitoring of research performed by a state educational institution as described in IC 21-45-7 concerning the safety and efficacy of using hemp oil in the treatment of intractable epilepsy.



(b) A physician or the state educational institution seeking to conduct research described in subsection (a) shall submit to the state department an application to be included in the pilot study registry that includes the following information:

- (1) The name of the pilot study.
- (2) The name of the affiliated state educational institution.
- (3) The scientific and clinical parameters of the study.
- (4) The protocols established to ensure patient safety.
- (5) The name and address of any physician associated with the pilot study.
- (6) Any other information considered necessary by the state department in order to determine the safety and evidence-based nature of the pilot study.

A physician may not conduct the research described in subsection (a) until the pilot study has been certified by the state department under subsection (c).

(c) The state department shall review each application submitted under subsection (b) and include the pilot study on the registry described in subsection (a) only after the state department determines and certifies that the proposed pilot study does the following:

- (1) Adheres to minimum scientific methods.
- (2) Protects patient safety.

(d) The state department may monitor a registered pilot study under this section to ensure that the physician adheres to the requirements set forth in subsection (c).

(e) A physician who has been approved for the pilot study registry shall do the following while conducting the pilot study research approved under this section:

- (1) Maintain records of the evaluations and observations of a patient participating in the pilot study, including the patient's response to the hemp oil treatment.
- (2) Transmit the records described in subdivision (1) to the state department upon the state department's request.

(f) The state department may charge a fee to cover implementation and administration of the registry established under this section.

Sec. 9. The state department shall maintain any medical records obtained under this chapter as confidential and the medical records may not be disclosed to the public.

Sec. 10. (a) A physician who is registered and conducting a registered pilot study under this chapter may approve the



1 dispensing or use of hemp oil to a registered caregiver or registered
2 patient for the treatment of intractable epilepsy.

3 (b) A physician registered under this chapter is immune from
4 civil, criminal, and administrative liability for approving,
5 dispensing, or using hemp oil in the treatment of a patient with
6 intractable epilepsy if the patient is validly registered under this
7 chapter.

8 Sec. 11. (a) The state department shall study whether the
9 registration under section 6 of this chapter should, based on sound
10 medical findings, be extended to patients who:

11 (1) are at least eighteen (18) years of age;

12 (2) have been examined and diagnosed by a physician to have
13 intractable epilepsy; and

14 (3) have been recommended by the physician for treatment by
15 hemp oil for the intractable epilepsy.

16 (b) Before November 1, 2016, the state department shall provide
17 its findings under subsection (a) to the general assembly in an
18 electronic format under IC 5-14-6.

19 Sec. 12. The state department may adopt rules under IC 4-22-2
20 necessary to implement this chapter.

21 SECTION 7. IC 21-45-7 IS ADDED TO THE INDIANA CODE AS
22 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY
23 1, 2015]:

24 **Chapter 7. Research on Hemp Oil for Treatment of Epilepsy**

25 Sec. 1. As used in this chapter, "hemp oil" means the oil from a
26 hemp plant.

27 Sec. 2. As used in this chapter, "intractable epilepsy" means a
28 seizure disorder that has been diagnosed by a physician (as defined
29 in IC 16-42-26-5) in a patient who has not responded to at least
30 three (3) other seizure disorder treatment options.

31 Sec. 3. The state encourages state educational institutions that
32 perform medical research and that are affiliated with a physician
33 registered under IC 16-42-26 to:

34 (1) conduct research by the physician; and

35 (2) participate in clinical studies or trials;

36 concerning the safety and efficacy of using hemp oil in the
37 treatment of intractable epilepsy.

38 SECTION 8. IC 34-30-2-84.1 IS ADDED TO THE INDIANA
39 CODE AS A NEW SECTION TO READ AS FOLLOWS
40 [EFFECTIVE JULY 1, 2015]: Sec. 84.1. IC 16-42-26-10 (Concerning
41 the dispensing or use of hemp oil in the treatment of intractable
42 epilepsy).



SECTION 9. IC 35-48-4-8.5, AS AMENDED BY P.L.158-2013,
SECTION 636, IS AMENDED TO READ AS FOLLOWS
[EFFECTIVE JULY 1, 2015]: Sec. 8.5. (a) A person who keeps for
sale, offers for sale, delivers, or finances the delivery of a raw material,
an instrument, a device, or other object that is intended to be or that is
designed or marketed to be used primarily for:

- (1) ingesting, inhaling, or otherwise introducing into the human
body marijuana, hash oil, hashish, salvia, a synthetic drug, or a
controlled substance;
- (2) testing the strength, effectiveness, or purity of marijuana, hash
oil, hashish, salvia, a synthetic drug, or a controlled substance;
- (3) enhancing the effect of a controlled substance;
- (4) manufacturing, compounding, converting, producing,
processing, or preparing marijuana, hash oil, hashish, salvia, a
synthetic drug, or a controlled substance;
- (5) diluting or adulterating marijuana, hash oil, hashish, salvia, a
synthetic drug, or a controlled substance by individuals; or
- (6) any purpose announced or described by the seller that is in
violation of this chapter;

commits a Class A infraction for dealing in paraphernalia.

(b) A person who knowingly or intentionally violates subsection (a)
commits a Class A misdemeanor. However, the offense is a Level 6
felony if the person has a prior unrelated judgment or conviction under
this section.

(c) This section does not apply to the following:

- (1) Items marketed for use in the preparation, compounding,
packaging, labeling, or other use of marijuana, hash oil, hashish,
salvia, a synthetic drug, or a controlled substance as an incident
to lawful research, teaching, or chemical analysis and not for sale.
- (2) Items marketed for or historically and customarily used in
connection with the planting, propagating, cultivating, growing,
harvesting, manufacturing, compounding, converting, producing,
processing, preparing, testing, analyzing, packaging, repackaging,
storing, containing, concealing, injecting, ingesting, or inhaling
of tobacco or any other lawful substance.

(3) A physician described in IC 16-42-26 who:

**(A) has been approved by the state department of health
under IC 16-42-26 to dispense or use hemp oil in the
treatment of a patient for intractable epilepsy in a pilot
study research described in IC 16-42-26; and**

**(B) is dispensing or otherwise using the hemp oil in the
treatment of the registered individual diagnosed with**



1 **intractable epilepsy.**
 2 **(4) A physician, patient, or caregiver who is registered under**
 3 **IC 16-42-26 for the use of hemp oil in the treatment of**
 4 **intractable epilepsy only if the hemp oil is being used:**
 5 **(A) for the person; and**
 6 **(B) in the manner;**
 7 **approved by the state department of health for the purposes**
 8 **of the registry.**

9 SECTION 10. IC 35-48-4-10, AS AMENDED BY P.L.168-2014,
 10 SECTION 100, IS AMENDED TO READ AS FOLLOWS
 11 [EFFECTIVE JULY 1, 2015]: Sec. 10. (a) A person who:

- 12 (1) knowingly or intentionally:
 13 (A) manufactures;
 14 (B) finances the manufacture of;
 15 (C) delivers; or
 16 (D) finances the delivery of;
 17 marijuana, hash oil, hashish, or salvia, pure or adulterated; or
 18 (2) possesses, with intent to:
 19 (A) manufacture;
 20 (B) finance the manufacture of;
 21 (C) deliver; or
 22 (D) finance the delivery of;
 23 marijuana, hash oil, hashish, or salvia, pure or adulterated;
 24 commits dealing in marijuana, hash oil, hashish, or salvia, a Class A
 25 misdemeanor, except as provided in subsections (b) through (d).
 26 (b) A person may be convicted of an offense under subsection (a)(2)
 27 only if there is evidence in addition to the weight of the drug that the
 28 person intended to manufacture, finance the manufacture of, deliver,
 29 or finance the delivery of the drug.
 30 (c) The offense is a Level 6 felony if:
 31 (1) the person has a prior conviction for a drug offense and the
 32 amount of the drug involved is:
 33 (A) less than thirty (30) grams of marijuana; or
 34 (B) less than five (5) grams of hash oil, hashish, or salvia; or
 35 (2) the amount of the drug involved is:
 36 (A) at least thirty (30) grams but less than ten (10) pounds of
 37 marijuana; or
 38 (B) at least five (5) grams but less than three hundred (300)
 39 grams of hash oil, hashish, or salvia.
 40 (d) The offense is a Level 5 felony if:
 41 (1) the person has a prior conviction for a drug dealing offense
 42 and the amount of the drug involved is:



- 1 (A) at least thirty (30) grams but less than ten (10) pounds of
- 2 marijuana; or
- 3 (B) at least five (5) grams but less than three hundred (300)
- 4 grams of hash oil, hashish, or salvia; or
- 5 (2) the:
- 6 (A) amount of the drug involved is:
- 7 (i) at least ten (10) pounds of marijuana; or
- 8 (ii) at least three hundred (300) grams of hash oil, hashish,
- 9 or salvia; or
- 10 (B) offense involved a sale to a minor.
- 11 **(e) This section does not apply to the following:**
- 12 **(1) A physician described in IC 16-42-26 who:**
- 13 **(A) has been approved by the state department of health**
- 14 **under IC 16-42-26 to dispense or use hemp oil in the**
- 15 **treatment of a patient for intractable epilepsy in a pilot**
- 16 **study research described in IC 16-42-26; and**
- 17 **(B) is dispensing or otherwise using the hemp oil in the**
- 18 **treatment of the registered individual diagnosed with**
- 19 **intractable epilepsy.**
- 20 **(2) A physician, patient, or caregiver who is registered under**
- 21 **IC 16-42-26 for the use of hemp oil in the treatment of**
- 22 **intractable epilepsy only if the hemp oil is being used:**
- 23 **(A) for the person; and**
- 24 **(B) in the manner;**
- 25 **approved by the state department of health for the purposes**
- 26 **of the registry.**
- 27 SECTION 11. IC 35-48-4-11, AS AMENDED BY
- 28 P.L.226-2014(ts), SECTION 12, IS AMENDED TO READ AS
- 29 FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 11. (a) A person who:
- 30 (1) knowingly or intentionally possesses (pure or adulterated)
- 31 marijuana, hash oil, hashish, or salvia;
- 32 (2) knowingly or intentionally grows or cultivates marijuana; or
- 33 (3) knowing that marijuana is growing on the person's premises,
- 34 fails to destroy the marijuana plants;
- 35 commits possession of marijuana, hash oil, hashish, or salvia, a Class
- 36 B misdemeanor, except as provided in subsections (b) through (c).
- 37 (b) The offense described in subsection (a) is a Class A
- 38 misdemeanor if the person has a prior conviction for a drug offense.
- 39 (c) The offense described in subsection (a) is a Level 6 felony if:
- 40 (1) the person has a prior conviction for a drug offense; and
- 41 (2) the person possesses:
- 42 (A) at least thirty (30) grams of marijuana; or



(B) at least five (5) grams of hash oil, hashish, or salvia.

(d) This section does not apply to the following:

(1) A physician described in IC 16-42-26 who:

(A) has been approved by the state department of health under IC 16-42-26 to dispense or use hemp oil in the treatment of a patient for intractable epilepsy in a pilot study research described in IC 16-42-26; and

(B) is dispensing or otherwise using the hemp oil in the treatment of the registered individual diagnosed with intractable epilepsy.

(2) A physician, patient, or caregiver who is validly registered under IC 16-42-26 for the use of hemp oil in the treatment of intractable epilepsy only if the hemp oil is being used:

(A) for the person; and

(B) in the manner;

approved by the state department of health for the purposes of the registry.

